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EXAMINER				
WARE, DEBORAH K				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/559,993

Applicant(s)

LOEFFLER, FRANK

Examiner

DEBBIE K. WARE

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-8 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8 and 16-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

SUPPLEMENTAL DETAILED ACTION

Claims 1, 3-8 and 16-20 are pending. Pursuant a meeting with the Biotechnology Specialist it was determined that a deposit issue and scope rejection should be made over the claims and hence this is a supplemental rejection to reintroduce these rejections on the record. While it is recognized that Applicants have stated they are having difficulty depositing the BAV1 strain because of required conditions for culturing the strain and maintaining it in a depository, there must be insurances that the strain be readily available to the public if a patent should issue in this case. Although the source of the BAV1 strain is from an identified subsurface aquifer material it is unclear that one of ordinary skill in the art would be able to obtain the strain if they should return to the identified source. The prior rejection(s) remain of record and this action is a supplemental to add additional rejections determined to be necessary for this case. Therefore, the strain is not readily available and the deposit issue has been reintroduced on the record as follows:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-8 and 16-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the microorganism is required and recited in each of the claims, it is essential to the whole invention as recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public. It is noted that applicants have deposited the organism but there is no indication in the specification as to public availability.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR § 1.807(b) which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

- (1) The name and address of the depository;
- (2) The name and address of the depositor;
- (3) The date of deposit;
- (4) The identity of the deposit and the accession number given by the depository;
- (5) The date of the viability test;
- (6) The procedures used to obtain a sample if the test is not done by the depository; and
- (7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CFR § 1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:

- (1) The accession number for the deposit;
- (2) The date of the deposit;
- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
- (4) The name and address of the depository.

Furthermore, claims 1, 3-8 and 16-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *Dehalococcoides* strain

BAV-1, does not reasonably provide enablement for any and all *Dehalococcoides* species and strains, thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice and carry out the invention commensurate in scope with these claims. The art clearly teaches that there are some *Dehalococcoides* strains, such as strain 195, which under certain conditions can not use vinyl chloride as an electron acceptor (Xavier Maymo-Gatell et al, page 3112, lines 3-4, cited of record already in the case on a PTO-1449 Form).

Thus, it would be undue burden of experimentation for one of ordinary skill in the art to have to culture and determine the kinetics of growth in culture under specific conditions for which to determine which strains can use vinyl chloride and which ones can not. Therefore, there is a high degree of unpredictability in the art that one of ordinary skill can select for an appropriate strain without undergoing great expense because of the undue burden of experimentation placed upon them for obtaining such a strain.

Hence, to practice and carry out the disclosed invention commensurate in scope with the claimed invention places too high of a burden on one of ordinary skill in the art, and the claims should be so limited to the strain BAV-1 which has been shown by Applicants to be within the scope of their disclosed invention. The claims are too broad for the enabling disclosure and one of skill in the art can not carry out the claimed invention without undue burden because of the high level of unpredictability in the art.

The following rejection is already of record in the last Office Action and is reiterated as follows:

Claim Rejections - 35 USC § 102/103

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 4, 5, 6, 7, 8, and 16-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sorenson (2002/0020665), cited on previously enclosed PTO-892 Form.

Claims are drawn to Dehalococcoides isolate for remediating a substrate comprising a halogenated compound which includes dichloroethene (DCE), and cis-DCE, vinyl-halide (halide can be chloride or bromide).

Sorenson teaches Dehalococcoides isolate for remediating a substrate comprising a halogenated compound which includes dichloroethene (DCE), and cis-

DCE, vinyl-halide, including vinyl-chloride. Note page 2, [0010], all lines and page 3, [0025], all lines, and specifically lines 4-5, and line 6 from the bottom of page 3, [0025].
The abstract and page 3, [0024], line 2.

The claims are indetical to the cited disclosures and are, therefore, considered to be anticipated by the teachings therein. However, in the alternative that there is some unidentified claim characteristic for which there would be some difference between the claims and the cited prior art, above, then such difference is considered to be so slight as to render the claims obvious in the alternative thereof. It would have been obvious to provide for a Dehalococcoides isolate for remediating a substrate comprising a halogenated compound which includes dichloroethene (DCE), and cis-DCE, vinyl-halide, including vinyl-chloride as shown and taught by the cited prior art. Each of the claimed features are disclosed by the cited prior art. The claims are rendered in the alternative prima facie obvious over the cited prior art.

Response to Arguments

Applicant's arguments filed January 16, 2009, have been fully considered but they are not persuasive. The argument that the referenced articles teach that Dehalococcoides ethenogenes can not use either trans-DCE or vinyl chloride as a metabolic electron acceptor is noted. However, Sorenson clearly teaches that in their experiments the two halogenated compounds are used as electron acceptors. Also the references referred to by Applicant's Representative came to this conclusion only because the trans-DCE and VC were not rapidly used by the cultures with strain 195 but this taken with the teachings of Sorenson does not exclude these two compounds as

being usable by the microbe as an electron acceptor. Thus, each of the claim features are clearly disclosed, with the exception of vinyl bromide which is believed by the Examiner to be at least an obvious, if not anticipated, electron acceptor given that vinyl halides are disclosed so broadly by the cited reference. The arguments are not persuasive and the rejection is sustained.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the **previously** enclosed PTO-892 Form. Therefore, the claims are properly rejected.

The remaining references listed on the previously enclosed PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **DEBBIE K. WARE** whose telephone number is (571)272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah K. Ware/
Deborah K. Ware
Examiner
Art Unit 1651